IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE: ARNTZEN, Charles T. et al.	)	
	)	**APPEAL NO. _____**
SERIAL NO: 10/733,135	)	
	)	
FOR: VACCINES EXPRESSED IN PLANTS	)	
	)	**REPLY BRIEF**
FILED: December 11, 2003	)	
	)	
GROUP ART UNIT: 1638	)	

To the Commissioner of Patents and Trademarks
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Dear Sirs and Madams:

Please enter the following Reply Brief on Appeal into the record, in response to the Examiner's Answers dated January 29, 2009 and March 19, 2009.

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I. INTRODUCTION

This is a Reply Brief in response to the Examiner's Answers dated January 29, 2009 and March 19, 2009 pursuant to 37 CFR 41.41(a). Appellants submit the Examiner's answers have failed to remedy the deficiencies with respect to the Final Office Action dated July 15, 2008 and as noted herein and in the Appellants' Appeal Brief. Appellants respectfully request that the rejections to claims 1-10 be reversed.

II. STATUS OF CLAIMS

Claims 1-14 were originally submitted December 11, 2003. In a Response to Office Action (Restriction Requirement) dated October 5, 2006, Appellant elected Group I (claims 1-10) and claims 11-14 were withdrawn. In an amendment dated June 20, 2007, Appellant amended claims 1, 4 and 8-10. In an Amendment accompanying a Request for Continued Examination filed October 31, 2007, Appellant amended claims 1, 6 and 8-9 and added claims 15-16. In an Amendment filed March 26, 2008 Appellant canceled claims 11-16. The final rejection mailed July 15, 2008 reinstated the rejections to claims 1-5 and 7-10 as obvious over Goodman et al. (U.S. Patent No. 4,956,282, issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546) and to claim 6 as obvious over Goodman et al. (U.S. Patent No. 4,956,282 issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546), as applied to claims 1-5 and 7-10 above, and further in view of Kay et al. (Science (1987), Vol. 236, pp. 1299-1302), and further in view of Gallie et al. (MGG (1991), Vol. 228, pp. 258-264). The claims here appealed are claims 1-10.

III. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-5, 7-8 and 10 are unpatentable over Goodman et al. (U.S. Patent No. 4,956,282, issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546).

B. Whether claims 6 and 9 are unpatentable over Goodman et al. (U.S. Patent No. 4,956,282 issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546), as applied to claims 1-5 and 7-10 above, and further in view of Kay et al. (Science (1987), Vol. 236, pp. 1299-1302), and further in view of Gallie et al. (MGG (1991), Vol. 228, pp. 258-264).

IV. ARGUMENT

A. The § 103 Rejection to Claims 1-5, 7-8 and 10 Based Upon Goodman et al. and Kapikian et al. Has Been Improperly Maintained

1. Goodman et al. and Kapikian et al. Individually or Combined Fail to Teach or Suggest "selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge."

In the Examiner's Answers, the Examiner indicates that the language "selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited" in the claim is interpreted as "inclusive of selecting plants with any expression level of a viral immunogen because the composition can comprise recombinant viral immunogen that has been purified and/or concentrated; therefore the amount of immunogen in the composition is not related a further limitation with regard to any specific or minimal expression level." Examiner's Answers, at page 5. Appellants disagree with the Examiner's interpretation of this phrase. Specifically, Appellants submit that the Examiner's interpretation of the claims simply ignores in Appellants' claims 1 and 8 the functional limitations of "such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited, so that the animal is protected against viral challenge" without regard to the teachings of *KSR Intern. Co. v. Teleflex Inc*, 82 U.S.P.Q.2d 1385 (2007) and MPEP 2173.05(g). MPEP § 2173.05(g) requires that the Examiner give patentable weight to functional language. See also *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971); *In re Caldwell*, 138 USPQ 243 (CCPA 1963); *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987 ("so that" functional clause of claim renders reference non-anticipating). In our view this functional language cannot be ignored and must be

considered in accordance with the MPEP and *KSR*. Appellants respectfully submit neither Goodman et al. nor Kapikian et al. disclose or suggest these functional limitations. Accordingly, claims 1 and 8 are not obvious for at least these reasons plus the elements in the claims.

2. Goodman et al. and Kapikian et al. Fails to Provide a Reasonable Expectation of Success for Appellants' Claimed Method

Alternatively, if the Board should conclude any expression level is encompassed by claims 1 and 8, the cited references provide no reasonable expectation of success for Appellants' claimed methods. Neither of these references provide any reasonable expectation that a viral immunogen could be expressed in a plant, orally administered to an animal, survive the animal's gut, and provide the animal protection against subsequent viral challenge. The Examiner's position that there is a reasonable expectation of success is unsupported and the obvious rejection improper.

The Examiner's concludes that it is obvious to take "the sequences encoding immunogens from the rotavirus taught by Kapikian et al." and express them in a plant using Goodman et al.'s method. Examiner's Answers, at pages 7-8. The Examiner states, "Given the success of producing recombinant therapeutic proteins in plants taught by Goodman et al. and the success of utilizing recombinant proteins for vaccines as taught by Kapikian et al., one would expect success in combining the teachings." Examiner's Answers, at page 8. Appellants strongly disagree with the Examiner's interpretation of these references.

Even if Goodman et al. do suggest expressing a viral immunogen, one skilled in the art would have no expectation of successfully expressing a viral immunogen based on Goodman et al.'s disclosure. First, Goodman et al. fail to provide in its disclose any level of protein expression achieved in a plant. One skilled in the art would not view the Goodman et al. disclosure as creating an expectation of success that an immunogen could be expressed at a level sufficient to generate an immune response in animal upon oral administration.

Second, even if Goodman et al. reference indicated that one could achieve in a plant sufficient expression levels of the immunogen, neither Goodman et al. nor Kapikian et al. provide a reasonable expectation of success that a plant-expressed immunogen would survive digestion in an animal's gut when administered orally and survive at levels that would be able to generate an immune response, much less a protective immune response against viral challenge.

Goodman et al. do not address this issue of survival and Kapikian et al. is not relevant because the Kapikian et al. reference teach the oral administration of attenuated, whole rotavirus strains used as vaccines. Rotaviral vaccines such as the one described in Kapikian et al. survive the gut because they are encapsulated in a protective viral particle. Thus, there is a difference between delivering an immunogen expressed in a plant and the same immunogen expressed in the context of a virus and encapsulated by a viral particle. Further to this point, in Kapikian et al. the mode of delivering the viral immunogen is different and the rotaviral immunogen is presented in a different context than in Appellants' claimed method, specifically expressing the immunogen in an attenuated whole virus versus Appellants' method of expressing a viral immunogen in a plant. Thus, Kapikian et al. is not predictive that an immunogen expressed in a plant and administered orally would survive the subject's stomach enzymes or acidic environment. Kapikian et al. is also not predictive that an immune response would be generated or that if produced would even be successful against viral challenge. Thus, one ordinarily skilled in the art would disregard Goodman et al. and Kapikian et al. as providing any expectation of success. Accordingly, there would be no expectation of success for a method of generating any immune response using an immunogen expressed from a plant and administered orally to an animal, much less a protective immune response that could protect against viral challenge.

Appellants note that this application claims a benefit of priority to August 26, 1991. It is critical when making an obviousness determination to cast one skilled in the art's mind back to the time of the invention, here, back to 1991. Indeed, *KSR* warns that factfinders "should be aware ... of the distortion caused by hindsight bias and must be cautious of

arguments reliant on *ex post* reasoning" and use of hindsight (as done here) is impermissible. *KSR*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007).

For all these reasons and those previously made of record, Goodman et al. and Kapikian et al. do not teach or suggest the functional limitations of independent claims 1 and 8, nor provide a reasonable expectation of success for a method of making an immunogenic composition by selecting plants expressing a recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge. Therefore, the claimed invention is not obvious. For at least these reasons plus the elements in the claims, independent claims 1 and 8 and dependent claims 2-5, 7 and 10 are patentable over Goodman et al. and Kapikian et al. The Examiner's rejection to these claims under § 103 rejection should be reversed.

B. The § 103 Rejection to Claims 6 and 9 Based Upon Goodman et al. and Kapikian et al. Has Been Improperly Maintained

Appellants continue to traverse the rejection under § 103(a) as the Examiner's arguments fail to render the claimed invention obvious. Appellants respectfully submit that the cited references are deficient with respect to the present claims because the references fail to disclose all claimed elements when the claims are properly interpreted.

For the reasons discussed herein above with respect to independent claims 1 and 8, Appellants respectfully submit that the Examiner has not properly interpreted claims 6 and 9 and has failed to give the functional limitations "selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge" proper patentable weight. Further, as discussed above, Appellants respectfully submit that Goodman et al. and Kapikian et al. fail to suggest these elements or provide a reasonable expectation of success that that an immunogen expressed in a plant and

administered orally would survive the subject's stomach enzymes or acidic environment. Kapikian et al. is also not predictive that an immune response would be generated or if produced would even be successful against viral challenge. These deficiencies are not remedied by Kay et al. or Gallie et al. Thus, one ordinarily skilled in the art would disregard Goodman et al., Kapikian et al., Kay et al. or Gallie et al. as providing any expectation of success. Therefore, there would be no expectation of success for a method of producing an immunogenic composition that when administered would generate any immune response using an immunogen expressed from a plant and administered orally to an animal, much less a protective immune response that could protect against viral challenge.

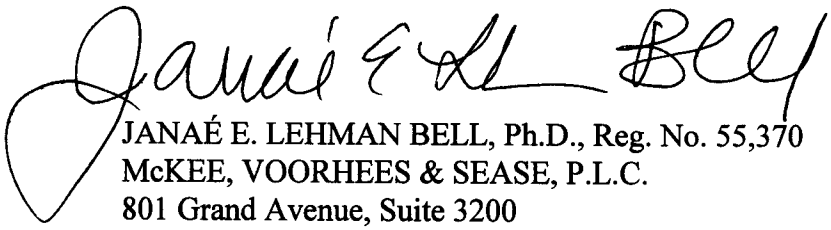
For at least these reasons and those previously made of record in Appellants' Appeal Brief, independent claims 1 and 9 and dependent claim 6 are not obvious and the rejection is improper. Accordingly, Appellants request the rejection to claims 6 and 9 under § 103 be reversed and the case allowed.

V. CONCLUSION

In view of the foregoing, Appellants respectfully submit that the Examiner's Answers doe not remedy the deficiencies noted herein and in Appellants' Appeal Brief. The Examiner's rejections under § 103 remain improper and should be reversed by the Board. It is respectfully submitted that the claims are in condition for allowance and the case should be allowed.

No fees or extensions of time are believed to be due in connection with this Replay Brief; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,



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